

Appl. No. 10/720,932  
Amdt. Dated 18-Aug-05  
Reply to Office Action of May 19, 2005  
Attorney Docket No. : 6051-009

### Remarks/Arguments

In the Examiner's Final Office Action dated May 19, 2005, the Examiner rejected Claims 1-11 under 35 U.S.C. §102(e) as being anticipated by Garrison et al. U.S. Patent No. 6,425,916.

### Background of the Law

In order to establish proper anticipation under 35 U.S.C. §102, each and every element of the claimed invention must be disclosed in a single prior art reference. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). The claimed elements either be inherent or disclosed expressly in the single prior art reference *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988) and must be arranged as in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). The absence from the reference of any claimed element necessarily negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 220 USPQ 81 (Fed. Cir. 1986).

### §102(e) Rejection: Garrison, et al. Fails to Disclose the Correspondingly Claimed Elements

Applicants have amended Claim 1 to clarify that the first second is distal the second section and that the first section is advanced substantially entirely distal the anatomic valve in claimed passing step. Applicants direct the Examiner's attention to the specific claim language defining the first and second sections. Specifically, the claim states:

... a *first section consisting* of the valvular prosthesis covered by a sheath, and a *second section consisting* of an inflatable balloon the first section being distal the second section ... [Emphasis added]

Applicants submit, therefore, that the Examiner's construction of the first and second sections in Garrison as reflected in the attachment to the Examiner's Final Office Action

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of May 19, 2005, is an extremely liberal interpretation of the reference, and at odds with the actual teaching of Garrison, et al., specifically at Figure 14 of the reference. Garrison, et al. teach a valvular prosthesis 6A which is concentrically disposed within the catheter 4A and underneath both the balloon 50 and the separate stent 8. The stent 8 is positioned concentrically around the balloon 50 and the catheter 4A. See, e.g., Fig. 14 of Garrison, et al. The atraumatic tip 84 does not form part of the operative section of the delivery system and is not employed in the method taught in the reference.

Thus, following the Examiner's interpretation of the first and second sections of Garrison, et al., the first section would include the valvular prosthesis 6A, the catheter 4A, the balloon 50 and the stent 8, whereas the second section would include the catheter 4A, the balloon 50 and the stent 8. This construction is in sharp contrast to the invention as claimed, in which the first section consists of the valvular prosthesis, the covering sheath and the catheter, and the second section consists of the balloon and the catheter. Applicant's use of the "consisting of" language requires that the first section consist only of the catheter, prosthesis and sheath and that the second section consist only of the catheter and the balloon. Thus, under the express language of the claims, the first and second sections must be independent of one another in the sense that the balloon of the second section cannot extend to the first section and the prosthesis of the second section cannot extend to the first section. Since, in Garrison, et al. the valvular prosthesis 6A and the stent 8 are implanted cooperatively, such that the valvular prosthesis 6A resides within the lumen of the stent 8 when implanted, as shown, for example in Figure 19 of the reference, Applicants interpret the both the valvular prosthesis 6A and the stent 8 to be the comparable elements to the valvular prosthesis as claimed in the pending claims.

Accordingly, Applicants respectfully submit that Claims 1-11 traverse each of the rejections of record and request that favorable reconsideration of the rejections be made and that pending Claims 1-11 be allowed to pass to issue.

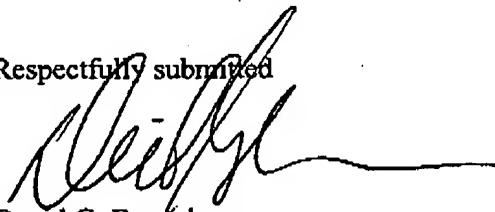
This Amendment Letter is being concurrently filed with a Notice of Change of Address, a Notice of Change of Entity Status, and an Amendment Transmittal which includes a fee calculation sheet and a Request for Extension of Time. Other than the

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extension fee identified in the Amendment Transmittal, no other fees are believed necessitated by this Amendment. Should, however, any such fees be required, the Director is hereby authorized to deduct them from the Deposit Account of Rosenbaum & Associates, P.C. No. 18-2000, of which the undersigned is an authorized signatory.

Should there be any further outstanding issues which the Examiner believes may be susceptible of resolution by a telephonic interview, the Examiner is encouraged to telephone the undersigned attorney-of-record at the below-identified telephone number regarding such matters.

Respectfully submitted



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